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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,364

09/22/2005

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

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1645

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/525,364	<b>Applicant(s)</b> DHAR ET AL.	
	<b>Examiner</b> S. Devi, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-26 and 28-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/23/05</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### Preliminary Amendments

- 1) Acknowledgment is made of Applicants' preliminary amendments filed 02/23/05, 01/31/08 and 05/12/08.

### Election

- 2) Acknowledgment is made of Applicants' election filed 01/31/08 in response to the written lack of unity mailed 09/12/07. Applicants have elected invention II, with traverse, claims 17-26 and 28-31, and the VP28 viral protein species. Applicants' traversal is on the grounds that: (a) invention groups I and II define one invention and do not possess sufficient differences to warrant issuance of separate patents; and (b) In accordance with MPEP 821.04, elected apparatus claims found to recite patentable subject matter may be rejoined with the provisionally withdrawn method of use claims and examined in one application provided the method of use limitations corresponding to those found to be patentable during examination of the elected invention.

Applicants' arguments have been carefully considered. As set forth previously, inventions I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of the first claimed invention is a method of protecting an animal from a disease comprising producing a disease-related protein or peptide in a transformed host cell and delivering the same to an animal. However, such a method was already disclosed in the prior art, for example, by Ryan *et al.* (US 6,036,953 – Applicants' IDS) or Cardenas *et al.* (*Vaccine* 11: 126-135, 1993 - Applicants' IDS). The special technical feature of invention II is a feed or feed additive comprising a recombinant protein or peptide capable of binding to a disease-causing agent, which was also known in the art at the time of instant invention as taught by Frenken *et al.* (US 6,517,829 - Applicants' IDS). Clearly, the special technical feature is not a unifying feature. Therefore, the lack of unity held in the instant application is proper and is hereby made FINAL.

Since Applicants have elected claims directed to the product, if the product claims are subsequently found allowable, the withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claims will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper lack of unity between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See ‘Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)’, 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder*. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### **Status of Claims**

**3)** Claim 1 has been amended via the amendment filed 05/12/08.

Claims 1-31 are pending.

Claims 1-16 and 27 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 17-26 and 28-31 are pending and are under examination. A first action on the merits is issued on these claims.

### **Information Disclosure Statement**

**4)** Acknowledgment is made of Applicants' Information Disclosure Statement filed 02/23/05. The information referred to therein has been considered and a signed copy is attached to this Office Action.

### **Priority**

**5)** The instant application is a national stage 371 application of PCT/US03/28868 filed 09/15/03 and claims priority to the provisional application 60/410,818 filed 09/16/2002.

### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

**6)** The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

**7)** Claims 18-20, 23-26 and 31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

a) Claims 18 and 24 are indefinite in the limitation: 'a portion' of a viral protein, because it is unclear what is encompassed in this limitation. How much of a viral protein's structure has to be retained such that the resultant product qualifies as 'a portion' of a viral protein is not clear. Does a single amino acid qualify as 'a portion' of a viral protein?

b) Claim 18 lacks proper antecedent basis in the limitation 'peptide'. Claim 18 depends from claim 17, which already includes the limitation. For proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation --the peptide--.

c) Analogous rejection and criticism apply to claims 18-20 and 24-26.

d) Claims 23 and 31 are vague, indefinite, and confusing in the limitation 'versions of these'. It is unclear what is encompassed in this limitation. How much of the protein's structure is contained in these 'versions' is not clear.

e) Claim 31 is indefinite and confusing in the limitation 'which is fed as purified or semi-purified protein ....'. Claim 31 depends from claim 30 (as opposed to claim 29) wherein the feed additive is limited to whole cells or broken cells. It is unclear how whole or broken cells can be fed as purified or semi-purified protein?

f) Claim 24 lacks proper antecedent basis in the limitation ‘a recombinant protein or peptide’. Claim 24 depends from claim 21, which already includes the limitation of ‘a recombinant protein or peptide’. Is ‘a recombinant protein or peptide’ recited in claim 24 different from the one recited in the base claim 21?

g) Claims 19 and 20, which depend from claim 18, and claims 25 and 26, which depend directly or indirectly from claim 24, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

### **Rejection(s) under 35 U.S.C. § 102**

**8)** The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

**9)** Claims 17-26 and 28-31 are rejected under 35 U.S.C. § 102(e)(2) as being anticipated by Frenken *et al.* (US 6,517,829 - Applicants’ IDS) as evidenced by van Hulten *et al.* (*J. General Virol.* 81: 2525-2529, 2000).

The transitional limitation ‘comprising’ similar to the limitations, such as, ‘having’ ‘including’, ‘containing’, or ‘characterized by’, represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (‘comprising’ leaves ‘the claim open for the inclusion of unspecified ingredients even in major amounts’). On the other hand, the limitation ‘consisting of’ represents closed claim language and excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948).

Frenken *et al.* disclosed a food, feed, or feed supplement (i.e., additive) comprising a recombinant protein or peptide capable of binding to a disease-causing agent, for example *E. coli*

K88. The protein or peptide comprises the sequence VTVSSAHHSEDPSSKCPKCP. The protein or peptide is at least semi-purified since it does not contain other antigens of *E. coli* K88 and is fed to piglets as whole yeast cells expressing the peptide on their surface. The protein or peptide protected the piglets against *E. coli* K88 infection. See abstract; second full paragraph in column 5; claims; and Examples including Examples 3 and 8. That the dipeptide sequences VS, PS, SS and VT from the sequence VTVSSAHHSEDPSSKCPKCP are an intrinsic part of the VP28 white spot syndrome virus sequence is inherent from the teachings of Frenken *et al.* in light of what is known in the art. For instance, van Hulten *et al.* demonstrate that sequences VS, PS, SS and VT constitute the dipeptide sequences or portions of VP28. See Figure 3 of van Hulten *et al.*

Claims 17-26 and 28-31 are anticipated by Frenken *et al.* van Hulten *et al.* is **not** used as a secondary reference in combination with Frenken *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Frenken *et al.* with the unrecited limitation(s) being inherent in view of what is known in the art as explained above. See *In re Samour* 197 USPQ 1 (CCPA 1978).

### Remarks

**10)** Claims 17-26 and 28-31 stand rejected.

**11)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (703) 872-9306.

**12)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**13)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/  
S. Devi, Ph.D.  
Primary Examiner  
AU 1645

September, 2008